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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/996,438 | 11/20/2001 | William Stefan Bess | 5724-03-EJF | 3857 |

7590

12/18/2002

Evan J. Federman
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EXAMINER

JONES, DWAYNE C

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 12/18/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/996,438

Applicant(s)

BESS ET AL.

Examiner

Dwayne C Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-19 are pending.
2. Claims 1-19 are rejected.

Response to Arguments

3. Applicant's arguments filed September 9, 2002 have been fully considered but they are not persuasive with respect to Nichols et al. of WO 97/37689 as well as Keown et al. of WO 95/11034. In particular, applicants have attempted to limit the claims to a combination inhibitor selected from an amino polymer and its transition metal salts as well as combination thereof in order to obviate the instant rejections.

4. The prior art rejection of Keown et al. of WO 95/11034 under 103 is maintained because of the following reasons. Keown et al. teach of a pharmaceutical composition which contains a sympathomimetic agent, such as ephedrine, and a mineral cation salt, namely chromium, (as cited from the abstract). In addition, Keown et al. also teach that this pharmaceutical composition contains various semipermeable polymers that are known in the art such as those of, inter alia, U.S. Patent No. 3,546,142, (as cited on page 15 of Keown et al.). U.S. Patent No. 3,546,142 lists the amine-containing polymer of polydimethylaminoethyl methacrylate, (see column 2, lines 13-14). Accordingly, Keown et al. again render the instant composition claims obvious because the skilled artisan would have been motivated to select a known material based on its suitability for its intended use, which supported a prima facie obviousness determination in *Sinclair &*

Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). In addition, composition claims are not deemed to be limited by an "intended use", see *In re Hack* 114 USPQ 161.

Claim Rejections - 35 USC § 102

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. The rejection of claim 1 under 35 U.S.C. 102(a) as being clearly anticipated by Nichols et al. of WO 97/37689 is withdrawn; however, this rejection of claims 1-19 is converted into a rejection under 35 U.S.C. 103 in response to the amendment of September 9, 2002.

7. The rejection of claim 1 under 35 U.S.C. 102(b) as being clearly anticipated by Hanna et al. of U.S. Patent No. 4,601,894 is withdrawn in response to the amendment of September 9, 2002.

8. The rejection of claim 1 under 35 U.S.C. 102(b) as being clearly anticipated by Keown et al. of WO 95/11034 is also withdrawn in response to the amendment of September 9, 2002.

9. The rejection of claim 1 under 35 U.S.C. 102(b) as being clearly anticipated by Nakamoto et al. of U.S. Patent No. 3,773,920 is removed in response to the amendment of September 9, 2002.

Claim Rejections - 35 USC § 103

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. The rejection of claim 1-19 under 35 U.S.C. 103 as being unpatentable over Keown et al. of WO 95/11034 is maintained for both the above-stated and reasons of record.

12. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nichols et al. of WO 97/37689. Nichols et al. teach of a composition that contains a sympathomimetic amine with other compounds, which make it difficult or essentially infeasible to synthesize illegal drugs from the sympathomimetic amine compounds, (see page 4, lines 1-23). In addition, Nichols et al. teach of various denaturants, in particular amine-containing compounds and well as various polymers, that are used to make the pure sympathomimetic amine salt difficult or essentially infeasible to isolate. Nichols et al. do not specifically teach of an amino polymer. The skilled artisan would have been motivated to utilize the teachings of Nichols et al. to utilize other types of denaturants, especially when Nichols et al. teach of various denaturants, in particular amine-containing compounds and various types of polymer-containing compounds because the purpose of the denaturant is to make it difficult or essentially infeasible to synthesize illegal drugs from the sympathomimetic amine compounds.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. U.S. Patent No. 6,359,011. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to salts of transition metals whereas U.S. Patent No. U.S. Patent No. 6,359,011 is directed to transition metal salts of iron, copper, cobalt, manganese, nickel and zinc.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

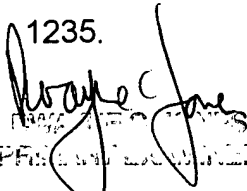
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.


WAYNE C. JONES
PATENT EXAMINER

Tech. Ctr. 1614

December 11, 2002